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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,175	01/22/2000	Richard Schmidt	P-8824	6836

7590

02/27/2002

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EXAMINER

RUDDY, DAVID M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/490,175

Applicant(s)

SCHMIDT

Examiner

David M Ruddy

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 1-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 77 and 78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of claims 77-78 in Paper No. 10 is acknowledged.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mo et al. (patent #6,321,116) in view of Tippey et al. (patent #5,702,428). Mo et al. disclose an apparatus and method for quantifying nerve and neural muscular integrity related to pelvic floor functions comprising placing a probe with a recording electrode into the vagina (column 8, lines 50-55); producing electrical stimulation pulses (via item 70) at a stimulation electrode ( see figures 1-7, 16b and 18); and detecting the resulting electrical activity in the pelvic floor by the recording electrode (as seen in figure 4 and via item 50). As seen by the data recorded and displayed in figure 4, (column 2, lines 55-67; column 8, lines 10-26; and column 10, lines 1-30) Mo et al. further disclose sampling the electrical signals at a relatively high rate (1600htz). By recording at such a high frequency in combination with the necessary amplification of the recorded signal, the memory of the device of Mo et al. will include the data of timing between the time of stimulation and electrical response of pelvic tissue.

The device of Mo et al. disclose that the stimulation electrode can be placed on the external patient surface (column 15, lines 23-42), however Mo et al. do not expressly disclose (that is to say, the words sacral or spinal do not appear in the printed patent document) the placement of the electrodes near the spinal cord or sacral nerve.

Tippey et al. (patent #5,702,428) disclose a method of treatment for urinary incontinence (just as in the Mo et al. reference). As set forth in column 7, lines 20-22, it is within the knowledge of one having ordinary skill in the art, that the sacral nerves are responsible for controlling the pelvic floor muscles that control incontinence.

Accordingly, it would have been obvious to one having ordinary skill in the art to place the stimulation electrode of Mo et al. near the sacral nerve (as taught by Tippey et al).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M Ruddy whose telephone number is (703) 308-3595. The examiner can normally be reached on Mon-Fri 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3376 for regular communications and (703) 746-3376 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

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DR

February 22, 2002

A handwritten signature in black ink, appearing to read 'Lee Cohen', with a long horizontal line extending to the right.

Lee Cohen  
Primary Examiner